

Appellant(s): Corriveau et al.

09/682,176

Appl. No.: Conf. No.:

9018

Filed:

July 31, 2001

Title:

METHODS OF PRODUCING TABLETED GUMS AND TABLETED GUMS

SO PRODUCED

Art Unit:

1761

Examiner:

A. Corbin

Docket No.: 112703-183

Mail Stop Appeal Brief - Patents Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

APPELLANTS' REPLY BRIEF

Dear Sir:

I. INTRODUCTION

This Reply Brief is submitted in support of the Notice of Appeal filed on July 7, 2004 following a Final Rejection dated March 22, 2004 and in response to the Examiner's Answer mailed on February 4, 2005. Because this Reply Brief is being submitted within two months from the Examiner's Answer, it is timely. A correct set of the pending claims is attached as Exhibit A.

A PRIMA FACIE CASE OF OBVIOUSNESS HAS NOT BEEN ESTABLISHED П.

Of course, every invention, whether patentable or not, in hindsight is obvious. Thus, the Federal Circuit has mandated "the mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." In re Fritch, 23 U.S.P.Q. 2d 1780, 1783-84 (Fed.Cir.

1992). Applicant submits that no art has been cited that suggests the desirability of the modifications needed to make the invention of Claims 1-26 obvious.

Claims 1-7, 9-15, 17, 18, 21-26 stand rejected as obvious over *Cherukuri*. *Cherukuri* is directed to tableted chewing gum compositions said to have the advantage that they can be used as a means for dispensing drugs, medicaments and other active agents. (Col. 9, lines 14-18) The active agents are trapped between the gum granules, being mixed with the tableting agent, and are not within the gum composition. The active agents are added in equal parts by weight with the compression aid and constitute 1 to 5% by weight of the resulting tablet. (Col. 9, lines 40-44)

The invention defined by each of the rejected claims requires a non-homogeneous distribution of tableting media and a non-homogeneous distribution of the gum component. Cherukuri simply does not disclose or suggest a tableted gum having a non-homogeneous distribution of tableting media or a non-homogeneous distribution of the gum component. Moreover, nonhomogeneous distributions would be undesirable in Cherukuri because the Cherukuri tableting media can be mixed with active agents and drugs which would result in a nonhomogeneus distribution of the active agents in the Cherukuri gum products. Generally speaking, it is much more desirable in formulations of active agents to have homogeneous distributions of active agents in a dosage form. This helps to ensure delivery of the entire amount of the active agent. Moreover, because no more than 15% by weight of tableting agent is used in the Cherukuri tablets, and more preferably 1% to 5%, the agent is more likely to be homogeneously distributed throughout the gum tablet to ensure that a tablet forms in the tableting process. Thus, it simply cannot be said that Cherukuri suggests or provides any motivation for the preparation of a tableted gum having a nonhomogeneous distribution of tableting media or a nonhomogeneous distribution of the gum component as required by each of the rejected claims.

Claims 8, 16, 19 and 20 stand rejected as obvious over *Cherukuri* in view of *Ream*. Each of these rejected claims is dependent on a base claim that requires a non-homogeneous distribution of tableting media and the gum component. Applicants submit that the rejection is inappropriate for two reasons. First, *Ream* does not remedy the deficiencies of *Cherukuri* set forth above, and secondly the combination itself is not appropriate. As set forth above, *Cherukuri* does not disclose or make obvious a tableted gum having a non-homogeneous

distribution of tableting media and gum component. Neither does *Ream*. In fact, *Ream* does not even disclose a tableted gum. Rather, *Ream* discloses a pourable confection composition having chewing gum particles in a free flowing, sweet confection. (Col. 1, lines 36-42) Consequently, there is no combination of *Ream* with *Cherukuri* that could provide the invention of Claims 8, 16, 19 and 20 which, *inter alia*, requires nonhomogeneous distributions of gum and tableting media. Moreover, neither the Examiner's Answer nor any of the Office actions has provided any rationale to support the combination of references relied upon by the Examiner, much less, in a way that would provide the presently claimed invention. It is the Examiner's burden in the first instance to provide some rational for the combination. That has not been done in this case. Applicant submits that there is, in fact, no reason to combine the teaching of a pourable confection as in *Ream* with the tableted gum formulation of *Cherukuri* and, in any event, such a combination would still not provide the presently claimed invention.

Claims 1-26 were rejected as obvious over *Ream* in view of *Cherukuri* or *Athanikar*. Each of Claims 1-26 requires a tableted gum having a non-homogeneous distribution of tableting media and the gum component. As indicated above, neither *Ream* nor *Cherukuri* contain this limitation or suggest it. Moreover, the references themselves provide no reason for their combination, nor has the Examiner provided the requisite support for the combination. In *Ream* new forms of confections are said to be popular with consumers. (Col. 1, line 11-15) The pourable *Ream* confection, if tableted as in *Cherukuri*, would lose what is considered by *Ream* to be its consumer appeal. Thus, Applicant submits the combination of *Ream* with *Cherukuri* is not proper.

As with Ream and Cherukuri, Athanikar fails to disclose chewing gum tablets having a non-homogeneous distribution of tableting media and the gum component. Rather, Athanikar discloses a tablet providing a dosage form of a pharmaceutical active ingredient having a more accurate uniform dose of the active ingredient. (Col. 4, lines 9-13) The hypothetical combination of Athanikar with the pourable confection of Ream, which contains gum particles and sugar powder, would defeat the purpose of Athanikar of providing a more uniform and accurate dose of a pharmaceutical active ingredient. Thus, the combination simply is not proper, and even if proper, still would not contain all the limitations of the claims as required to support the existing rejection for obviousness.

III. SUMMARY

In making a determination that an invention is obvious, the Patent Office has the initial burden of establishing a *prima facie* case of obviousness. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S. P.Q.2d 1955, 1956 (Fed. Cir. 1993). To establish a *prima facie* case of obviousness, several basic criteria must be met. There must be some suggestion or motivation, either in the reference or references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. *In re Fine*, 837 F.2d 1071, 5, U.S.P.Q.2d 1596 (Fed. Cir. 1988). In addition, all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q., 580 (CCPA 1974).

In the present case, the Examiner has failed to establish a *prima facie* case of obviousness to support the rejections for two reasons. First, the cited references fail to teach or suggest every element of the claimed invention. Second, there is no teaching or suggestion within the cited references or within the general knowledge of those skilled in the art that would have led one skilled in the art to make the suggested combination.

The Federal Circuit has held that it is "impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." *In re Fritch*, 23 U.S.P.Q.2d 1780, 1784 (Fed. Cir. 1992). If the examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more Applicants are entitled to grant of the patent. *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992).

IV. CONCLUSION

For these reasons Applicants submit that Claims 1-26 are not obvious and are patentable, and request that this Board reverse the rejections and allow the patent.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY

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Date: April 4, 2005

APR 0 4 2005

PENDING CLAIMS OF U.S. PATENT APPLICATION SERIAL NO. 09/682,176

Claim 1: A tableted gum comprising:

- a gum component including one or more gum chips; and
- a tableting media wherein the tableting media has an average particle size that is smaller in size than the average particle size of the gum chips, the tableted gum having a non-homogeneous distribution of the gum component and the tableting media.
- Claim 2: The tableted gum of claim 1 wherein the tableting media comprises a tableting powder.
- Claim 3: The tableted gum of claim 2 wherein the tableting powder is composed of particles that are smaller in size than the gum chips of the gum component.
- Claim 4: The tableted gum of claim 1 wherein the gum component comprises about 40% to about 60% by weight of the tableted gum.
- Claim 5: The tableted gum of claim 1 wherein the tableting media comprises about 40% to about 60% by weight of the tableted gum.
- Claim 6: The tableted gum of claim 1 wherein the gum component comprises about 40% by weight of the tableted gum and the tableting media comprises about 60% by weight of the tableted gum.
- Claim 7: The tableted gum of claim 6 wherein the tableted gum comprises a top portion which contains a substantial amount of the gum chips of the gum component.
- Claim 8: The tableted gum of claim 7 wherein the tableting media comprises a tableting powder, the gum chips being differently colored than the tableting powder.
 - Claim 9: The tableted gum of claim 1 further comprising a food grade lubricant.
- Claim 10: The tableted gum of claim 9 wherein the food grade lubricant is selected from the group consisting of magnesium stearate, calcium stearate, stearic acid, carboxy methyl cellulose and mixtures thereof.

- Claim 11: The tableted gum of claim 1 wherein the tableted gum comprises a sugar tableted gum or a sugar free tableted gum.
- Claim 12: A gum comprising a mixture of gum chips and tableting media in a tableted form, the gum having a non-homogeneous distribution of the gum chips and tableting media, and wherein the gum chips have an average particle size greater than the average particle size of the tableting media.
- Claim 13: The gum of claim 12 wherein the average particle size of the gum chips ranges from about 0.5 mm to about 6.0 mm.
- Claim 14: The gum of claim 12 wherein the gum chips comprise about 40% to about 60% by weight of the tableted gum and the tableting media comprises about 40% to about 60% by weight of the tableted gum.
 - Claim 15: A method of producing a tableted gum comprising the steps of: providing a gum component;

processing the gum component to form one or more gum chips;

mixing the gum chips with a tableting media wherein the tableting media has an average particle size that is smaller in size than the average particle size of the gum chips; and

processing the mixture of gum chips and tableting media to form a non-homogeneous distribution of the gum component and the tableting media in the tableted gum.

- Claim 16: The method of claim 15 wherein the gum component is chilled prior to forming the gum chips.
- Claim 17: The method of claim 15 wherein the mixture of gum chips and tableting media is punched or pressed to form the tableted gum.
- Claim 18: The method of claim 17 wherein the tableted gum comprises a top portion that is concentrated with the gum chips of the gum component.
- Claim 19: The method of claim 18 wherein the gum component comprises a different color than the tableting media.

- Claim 20: The method of claim 18 wherein the gum component and the tableting media have a same or similar color.
- Claim 21: The method of claim 15 wherein the mixture of gum chips and tableting media includes a food grade lubricant to facilitate forming the tableted gum.
- Claim 22: The method of claim 21 wherein the food grade lubricant is selected from the group consisting of magnesium stearate, calcium stearate, stearic acid, carboxy methyl cellulose and combinations thereof.
- Claim 23: The method of claim 22 wherein the food grade lubricant comprises magnesium stearate ranging from about 10% or less by weight of the tableting media.
- Claim 24: The method of claim 15 wherein the gum component comprises about 40% to about 60% by weight of the tableted gum and the tableting media comprises about 40% to about 60% by weight of the tableted gum.
- Claim 25: The method of claim 24 wherein the gum component comprises about 40% by weight of the tableted gum and the tableting media comprises about 60% by weight of the tableted gum.
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II. A PRIMA FACIE CASE OF OBVIOUSNESS HAS NOT BEEN ESTABLISHED

Of course, every invention, whether patentable or not, in hindsight is obvious. Thus, the Federal Circuit has mandated "the mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-84 (Fed.Cir.

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distribution of tableting media and gum component. Neither does Ream. In fact, Ream does not even disclose a tableted gum. Rather, Ream discloses a pourable confection composition having chewing gum particles in a free flowing, sweet confection. (Col. 1, lines 36-42) Consequently, there is no combination of Ream with Cherukuri that could provide the invention of Claims 8, 16, 19 and 20 which, inter alia, requires nonhomogeneous distributions of gum and tableting media. Moreover, neither the Examiner's Answer nor any of the Office actions has provided any rationale to support the combination of references relied upon by the Examiner, much less, in a way that would provide the presently claimed invention. It is the Examiner's burden in the first instance to provide some rational for the combination. That has not been done in this case. Applicant submits that there is, in fact, no reason to combine the teaching of a pourable confection as in Ream with the tableted gum formulation of Cherukuri and, in any event, such a combination would still not provide the presently claimed invention.

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PENDING CLAIMS OF U.S. PATENT APPLICATION SERIAL NO. 09/682,176

- Claim 1: A tableted gum comprising:
- a gum component including one or more gum chips; and
- a tableting media wherein the tableting media has an average particle size that is smaller in size than the average particle size of the gum chips, the tableted gum having a non-homogeneous distribution of the gum component and the tableting media.
- Claim 2: The tableted gum of claim 1 wherein the tableting media comprises a tableting powder.
- Claim 3: The tableted gum of claim 2 wherein the tableting powder is composed of particles that are smaller in size than the gum chips of the gum component.
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- Claim 10: The tableted gum of claim 9 wherein the food grade lubricant is selected from the group consisting of magnesium stearate, calcium stearate, stearic acid, carboxy methyl cellulose and mixtures thereof.

Claim 11: The tableted gum of claim 1 wherein the tableted gum comprises a sugar tableted gum or a sugar free tableted gum.

Claim 12: A gum comprising a mixture of gum chips and tableting media in a tableted form, the gum having a non-homogeneous distribution of the gum chips and tableting media, and wherein the gum chips have an average particle size greater than the average particle size of the tableting media.

Claim 13: The gum of claim 12 wherein the average particle size of the gum chips ranges from about 0.5 mm to about 6.0 mm.

Claim 14: The gum of claim 12 wherein the gum chips comprise about 40% to about 60% by weight of the tableted gum and the tableting media comprises about 40% to about 60% by weight of the tableted gum.

Claim 15: A method of producing a tableted gum comprising the steps of: providing a gum component;

processing the gum component to form one or more gum chips;

mixing the gum chips with a tableting media wherein the tableting media has an average particle size that is smaller in size than the average particle size of the gum chips; and

processing the mixture of gum chips and tableting media to form a non-homogeneous distribution of the gum component and the tableting media in the tableted gum.

Claim 16: The method of claim 15 wherein the gum component is chilled prior to forming the gum chips.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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III. <u>SUMMARY</u>

In making a determination that an invention is obvious, the Patent Office has the initial burden of establishing a *prima facie* case of obviousness. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S. P.Q.2d 1955, 1956 (Fed. Cir. 1993). To establish a *prima facie* case of obviousness, several basic criteria must be met. There must be some suggestion or motivation, either in the reference or references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. *In re Fine*, 837 F.2d 1071, 5, U.S.P.Q.2d 1596 (Fed. Cir. 1988). In addition, all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q., 580 (CCPA 1974).

In the present case, the Examiner has failed to establish a *prima facie* case of obviousness to support the rejections for two reasons. First, the cited references fail to teach or suggest every element of the claimed invention. Second, there is no teaching or suggestion within the cited references or within the general knowledge of those skilled in the art that would have led one skilled in the art to make the suggested combination.

The Federal Circuit has held that it is "impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." *In re Fritch*, 23 U.S.P.Q.2d 1780, 1784 (Fed. Cir. 1992). If the examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more Applicants are entitled to grant of the patent. *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992).

IV. <u>CONCLUSION</u>

For these reasons Applicants submit that Claims 1-26 are not obvious and are patentable, and request that this Board reverse the rejections and allow the patent.

Respectfully submitted,

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Date: April 4, 2005



PENDING CLAIMS OF U.S. PATENT APPLICATION SERIAL NO. 09/682,176

Claim 1: A tableted gum comprising:

a gum component including one or more gum chips; and

a tableting media wherein the tableting media has an average particle size that is smaller in size than the average particle size of the gum chips, the tableted gum having a non-homogeneous distribution of the gum component and the tableting media.

- Claim 2: The tableted gum of claim 1 wherein the tableting media comprises a tableting powder.
- Claim 3: The tableted gum of claim 2 wherein the tableting powder is composed of particles that are smaller in size than the gum chips of the gum component.
- Claim 4: The tableted gum of claim 1 wherein the gum component comprises about 40% to about 60% by weight of the tableted gum.
- Claim 5: The tableted gum of claim 1 wherein the tableting media comprises about 40% to about 60% by weight of the tableted gum.
- Claim 6: The tableted gum of claim 1 wherein the gum component comprises about 40% by weight of the tableted gum and the tableting media comprises about 60% by weight of the tableted gum.
- Claim 7: The tableted gum of claim 6 wherein the tableted gum comprises a top portion which contains a substantial amount of the gum chips of the gum component.
- Claim 8: The tableted gum of claim 7 wherein the tableting media comprises a tableting powder, the gum chips being differently colored than the tableting powder.
 - Claim 9: The tableted gum of claim 1 further comprising a food grade lubricant.
- Claim 10: The tableted gum of claim 9 wherein the food grade lubricant is selected from the group consisting of magnesium stearate, calcium stearate, stearic acid, carboxy methyl cellulose and mixtures thereof.

Claim 11: The tableted gum of claim 1 wherein the tableted gum comprises a sugar tableted gum or a sugar free tableted gum.

Claim 12: A gum comprising a mixture of gum chips and tableting media in a tableted form, the gum having a non-homogeneous distribution of the gum chips and tableting media, and wherein the gum chips have an average particle size greater than the average particle size of the tableting media.

Claim 13: The gum of claim 12 wherein the average particle size of the gum chips ranges from about 0.5 mm to about 6.0 mm.

Claim 14: The gum of claim 12 wherein the gum chips comprise about 40% to about 60% by weight of the tableted gum and the tableting media comprises about 40% to about 60% by weight of the tableted gum.

Claim 15: A method of producing a tableted gum comprising the steps of: providing a gum component;

processing the gum component to form one or more gum chips;

mixing the gum chips with a tableting media wherein the tableting media has an average particle size that is smaller in size than the average particle size of the gum chips; and

processing the mixture of gum chips and tableting media to form a non-homogeneous distribution of the gum component and the tableting media in the tableted gum.

Claim 16: The method of claim 15 wherein the gum component is chilled prior to forming the gum chips.

Claim 17: The method of claim 15 wherein the mixture of gum chips and tableting media is punched or pressed to form the tableted gum.

Claim 18: The method of claim 17 wherein the tableted gum comprises a top portion that is concentrated with the gum chips of the gum component.

Claim 19: The method of claim 18 wherein the gum component comprises a different color than the tableting media.

Claim 20: The method of claim 18 wherein the gum component and the tableting media have a same or similar color.

Claim 21: The method of claim 15 wherein the mixture of gum chips and tableting media includes a food grade lubricant to facilitate forming the tableted gum.

Claim 22: The method of claim 21 wherein the food grade lubricant is selected from the group consisting of magnesium stearate, calcium stearate, stearic acid, carboxy methyl cellulose and combinations thereof.

Claim 23: The method of claim 22 wherein the food grade lubricant comprises magnesium stearate ranging from about 10% or less by weight of the tableting media.

Claim 24: The method of claim 15 wherein the gum component comprises about 40% to about 60% by weight of the tableted gum and the tableting media comprises about 40% to about 60% by weight of the tableted gum.

Claim 25: The method of claim 24 wherein the gum component comprises about 40% by weight of the tableted gum and the tableting media comprises about 60% by weight of the tableted gum.

Claim 26: The method of claim 15 wherein the gum chips have an average particle size that ranges from about 0.5 mm to about 6.0 mm.